Application No. 10/585,464 2 Docket No.: C1285.70006US01

Amendment dated May 25, 2010 Reply to Office Action of November 25, 2009

AMENDMENTS TO THE CLAIMS

Please replace all prior versions, and listings, of claims in the application with the following list of claims:

- (Previously presented) A method for facilitating the diagnosis of a patient for a cancer of
 epithelial origin comprising:
 - a. obtaining a biological sample from the patient; and
 - b. detecting the presence or absence of ADAM 12 in the biological sample, wherein the presence of ADAM 12 is indicative of the presence of cancer of epithelial origin, wherein said biological sample is selected from the group consisting of blood, serum, urine, stool, sputum, cerebrospinal fluid, nipple aspirates and supernatant from cell lysate, and wherein the cancer is not colon cancer.
- (Cancelled)
- 3. (Previously presented) The method of claim 1, wherein said biological sample is urine.
- (Previously presented) A method for diagnosing cancer of epithelial origin in a patient comprising:
 - a. measuring ADAM 12 levels present in a test sample obtained from the patient;
- comparing the level of ADAM 12 in the test sample with the level of ADAM 12 present in a control sample;

wherein a higher level of ADAM 12 in the test sample as compared to the level of

ADAM 12 in the control sample is indicative of cancer of epithelial origin, wherein said test sample and said control sample are selected from the group consisting of blood, serum, urine, stool, sputum, cerebrospinal fluid, nipple aspirates and supernatant from cell lysate, and wherein the cancer is not colon cancer.

(Cancelled)

1932077 1

Docket No.: C1285.70006US01

Application No. 10/585,464 Amendment dated May 25, 2010 Reply to Office Action of November 25, 2009

6. (Original) The method of claim 4, wherein said test and control samples are urine.

3

- 7. (Previously presented) A method for prognostic evaluation of a patient suspected of having or having cancer of epithelial origin comprising:
 - a. measuring a level of ADAM 12 present in a test sample obtained from the patient;
 - comparing the level determined in step (a) to a level of ADAM 12 in a control sample; and
 - c. evaluating the prognosis of said patient based on the comparison of step (b), wherein a level of ADAM 12 in the test sample that is at least 3 fold greater than the level of ADAM 12 in a control sample indicates an aggressive form of cancer and therefore a poor prognosis, wherein said test sample and said control sample are selected from the group consisting of blood, serum, urine, stool, sputum, cerebrospinal fluid, nipple aspirates and supernatant from cell lysate, and wherein the cancer is not colon cancer.

(Cancelled)

- 9. (Previously presented) The method of claim 1, 4, or 7, wherein the cancer of epithelial origin is selected from the group consisting of breast cancer, basal cell carcinoma, adenocarcinoma, gastrointestinal cancer, lip cancer, mouth cancer, esophageal cancer, small bowel cancer, stomach cancer, liver cancer, bladder cancer, pancreas cancer, ovary cancer, cervical cancer, lung cancer, skin cancer, prostate cancer, and renal cell carcinoma.
- 10. (Original) The method of claim 1, wherein the presence or absence of ADAM 12 is detected using an antibody-based binding moiety which specifically binds ADAM 12.

Reply to Office Action of November 25, 2009

11. (Previously presented) The method of any of claims 1, 4, or 7, wherein the level of ADAM 12 is measured by measuring the level of ADAM 12 protein.

- 12. (Original) The method of claim 11, wherein the level of ADAM 12 protein is measured by a method comprising the steps of:
 - a. contacting the test sample, or preparation thereof, with an antibody-based binding moiety which specifically binds ADAM 12 to form an antibody-ADAM 12 complex; and
 - detecting the presence of the complex, thereby measuring the level of ADAM
 12 present.
- 13. (Previously presented) The method according to claim 12, wherein the antibody-based binding moiety is labeled with a detectable label.
- 14. (Original) The method according to claim 13, wherein the label is selected from the group consisting of a radioactive label, a hapten label, a fluorescent label, and an enzymatic label.
- 15. (Previously presented) The method according to claim 12, wherein the antibody-based binding moiety is an antibody.
- (Original) The method according to claim 15, wherein the antibody is an monoclonal antibody.

17-19. (Cancelled)

 (Previously presented) The method according to claim 1, wherein the biological sample is urine. Application No. 10/585,464 Amendment dated May 25, 2010 Reply to Office Action of November 25, 2009

- (Previously presented) The method according to claim 1, wherein the biological sample is blood.
- (Previously presented) The method according to claim 1, wherein the biological sample is serum.
- (Previously presented) The method according to claim 1, wherein the cancer is breast cancer
- (Previously presented) The method according to claim 1, wherein the cancer is bladder cancer.
- (Previously presented) The method according to claim 1, wherein the cancer is prostate cancer.
- (Previously presented) The method according to claim 4, wherein the test sample and control sample are urine.
- 27. (Previously presented) The method according to claim 4, wherein the test sample and control sample are blood.
- (Previously presented) The method according to claim 4, wherein test sample and control sample are serum.
- (Previously presented) The method according to claim 4, wherein the cancer is breast cancer.
- (Previously presented) The method according to claim 4, wherein the cancer is bladder cancer.

Application No. 10/585,464 6 Docket No.: C1285.70006US01

Amendment dated May 25, 2010 Reply to Office Action of November 25, 2009

31. (Previously presented) The method according to claim 4, wherein the cancer is prostate

cancer.

32. (Previously presented) The method according to claim 7, wherein the test sample and

control sample are urine.

33. (Previously presented) The method according to claim 7, wherein the test sample and

control sample are blood.

34. (Previously presented) The method according to claim 7, wherein test sample and control

sample are serum.

35. (Previously presented) The method according to claim 7, wherein the cancer is breast

cancer.

36. (Previously presented) The method according to claim 7, wherein the cancer is bladder

cancer.

37. (Previously presented) The method according to claim 7, wherein the cancer is prostate

cancer.

38. (Previously presented) A method for facilitating the diagnosis of a patient for a cancer

of epithelial origin comprising:

a. obtaining a biological sample from the patient; and

detecting the presence or absence of ADAM 12 in the biological sample, wherein the
presence of ADAM 12 is indicative of the presence of cancer of epithelial origin, and

presence of ADAM 12 is indicative of the presence of cancer of epithelial origin, and wherein said biological sample is selected from the group consisting of urine.

sputum, cerebrospinal fluid, and nipple aspirates.

1932077.1

7 Docket No.: C1285.70006US01

Application No. 10/585,464 Amendment dated May 25, 2010 Reply to Office Action of November 25, 2009

- (Previously presented) The method according to claim 38, wherein the biological sample is urine.
- (Previously presented) A method for diagnosing cancer of epithelial origin in a patient comprising:
 - a. measuring ADAM 12 levels present in a test sample obtained from the patient;
- comparing the level of ADAM 12 in the test sample with the level of ADAM 12 present in a control sample;

wherein a higher level of ADAM 12 in the test sample as compared to the level of ADAM 12 in the control sample is indicative of cancer of epithelial origin, wherein said test sample and said control sample are selected from the group consisting of urine, sputum, cerebrospinal fluid, and nipple aspirates.

- (Previously presented) The method according to claim 40, wherein the biological sample is urine.
- 42. (Previously presented) A method for prognostic evaluation of a patient suspected of having or having cancer of epithelial origin comprising:
 - a. measuring a level of ADAM 12 present in a test sample obtained from the patient;
 - comparing the level determined in step (a) to a level of ADAM 12 in a control sample; and
- c. evaluating the prognosis of said patient based on the comparison of step (b), wherein a level of ADAM 12 in the test sample that is at least 3 fold greater than the level of ADAM 12 in a control sample indicates an aggressive form of cancer and therefore a poor prognosis, wherein said test sample and said control sample are selected from the group consisting of urine, sputum, cerebrospinal fluid, and nipple aspirates.

Application No. 10/585,464 8 Docket No.: C1285.70006US01

Amendment dated May 25, 2010 Reply to Office Action of November 25, 2009

> (Previously presented) The method according to claim 42, wherein the biological sample is urine.

- 44. (New) The method of claim 38, wherein the cancer of epithelial origin is selected from the group consisting of breast cancer, basal cell carcinoma, adenocarcinoma, gastrointestinal cancer, lip cancer, mouth cancer, esophageal cancer, small bowel cancer, stomach cancer, colon cancer, liver cancer, bladder cancer, pancreas cancer, ovary cancer, cervical cancer, lung cancer, skin cancer, prostate cancer, and renal cell carcinoma.
 - 45. (New) The method according to claim 38, wherein the cancer is breast cancer.
 - 46. (New) The method according to claim 38, wherein the cancer is bladder cancer.
 - 47. (New) The method according to claim 38, wherein the cancer is prostate cancer.
- 48. (New) The method of claim 40, wherein the cancer of epithelial origin is selected from the group consisting of breast cancer, basal cell carcinoma, adenocarcinoma, gastrointestinal cancer, lip cancer, mouth cancer, esophageal cancer, small bowel cancer, stomach cancer, colon cancer, liver cancer, bladder cancer, pancreas cancer, ovary cancer, cervical cancer, lung cancer, skin cancer, prostate cancer, and renal cell carcinoma.
 - 49. (New) The method according to claim 40, wherein the cancer is breast cancer.
 - 50. (New) The method according to claim 40, wherein the cancer is bladder cancer.
 - 51. (New) The method according to claim 40, wherein the cancer is prostate cancer.
- 52. (New) The method of claim 42, wherein the cancer of epithelial origin is selected from the group consisting of breast cancer, basal cell carcinoma, adenocarcinoma,

9 Docket No.: C1285.70006US01

Application No. 10/585,464 Amendment dated May 25, 2010 Reply to Office Action of November 25, 2009

gastrointestinal cancer, lip cancer, mouth cancer, esophageal cancer, small bowel cancer, stomach cancer, colon cancer, liver cancer, bladder cancer, pancreas cancer, ovary cancer, cervical cancer, lung cancer, skin cancer, prostate cancer, and renal cell carcinoma.

- 53. (New) The method according to claim 42, wherein the cancer is breast cancer.
- 54. (New) The method according to claim 42, wherein the cancer is bladder cancer.
- 55. (New) The method according to claim 42, wherein the cancer is prostate cancer.